<u>S/N 10/749,093</u> <u>PATENT</u>

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Richard E. Stein et al. Examiner: Lenwood Faulcon

Serial No.: 10/749,093 Group Art Unit: 3762 Filed: December 17, 2003 Docket: 279.B31US2

Title: PATIENT CONTROLLED THERAPY MANAGEMENT AND DIAGNOSTIC

DEVICE WITH HUMAN FACTORS INTERFACE

## PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

The applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request. This request is being filed with a Notice of Appeal. Review is requested for the reason(s) stated below:

## 1. The § 103 Rejection of claims 1-20 using Stanton in view of Nappholz.

Appellant respectfully submits that there is no *prima facie* case of obviousness of claims 1-20 because (1) Stanton and/or Nappholz fail to disclose, teach, or suggest all elements of the present claims; and (2) there exists no motivation to combine these references in the manner used in the rejection.

In particular, Appellant cannot find in the cited portions of these references any disclosure, teaching, or suggestion of "a plurality of deadfront status indicator lamps ... each including a deadfront icon that is illuminated for viewing on a front of the case" as recited in claim 1 and similarly recited in claims 13 and 18. Instead, Stanton apparently merely describes the use of light emitting diodes (LEDs) to indicate whether a particular programming event has occurred (see Stanton at col. 14, lines 47-53). Several LEDs are apparently arranged with corresponding text on the body of the programmer (see Stanton at FIG. 3 at 32, 34, 36, 38). There is no indication that the LEDs in Stanton are used to illuminate an icon or other symbolic picture. Instead, Stanton's LEDs are simply exposed to the user to provide a binary state indication (e.g., on or off) (see Stanton at col. 6, lines 26-37). Moreover, Nappholz fails to disclose, teach, or suggest using LEDs to illuminate icons. Instead, Nappholz's device uses a graphical display (see Nappholz at FIG. 5 at 66) to provide information (see Nappholz at col. 6,

Filing Date: December 17, 2003

Title: PATIENT CONTROLLED THERAPY MANAGEMENT AND DIAGNOSTIC DEVICE WITH HUMAN FACTORS INTERFACE

lines 49-50; col. 9, lines 53-59). Nappholz's use of such a display obviates any need for LEDs and, even when combined with Stanton, fails to yield the claimed "plurality of deadfront status indicator lamps ... each including a deadfront icon that is illuminated for viewing on a front of the case." Thus, neither Stanton nor Nappholz provide disclosure of the claimed elements, either individually or in combination.

Moreover, Appellant respectfully submits that the references provide absolutely no motivation to combine Stanton with Nappholz. The Final Office Action must provide specific, objective evidence of record for a finding of a suggestion or motivation to combine reference teachings and must explain the reasoning by which the evidence is deemed to support such a finding. *In re Sang Su Lee*, 277 F.3d 1338, 61 USPQ2d 1430 (Fed. Cir. 2002). However, the Final Office Action merely asserts:

... it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Stanton et al. to include various warning/issue indicators to provide messages to a patient...

(Final Office Action at page 3). Appellant respectfully disagrees with this vague and conclusory assertion, which is unsupported by any objective evidence. One of ordinary skill in the art certainly would not attempt to "improve" Stanton in this manner. As discussed above, Stanton apparently describes a system that includes "various warning/issue indicators to provide messages to a patient." However, in contrast to the illuminated icons that the present application describes, Stanton's device uses bare LEDs that provide a binary indication (on/off) or blink in patterns to reflect IPG status (see Stanton at col. 14, line 47 to col. 15, line 6). Appellant cannot find anything in Stanton indicating recognition of any limited usefulness of bare LEDs. One of ordinary skill in the art would not necessarily look to improve Stanton's indicators as Stanton already provides indicators in one form—without any recognition of the serious shortcomings of its indicators.

Furthermore, even if someone were attempting to improve Stanton, one would not look to Nappholz to improve Stanton in this area. Stanton's device, which uses bare LEDs, is arguably sufficient for its very basic and limited intended purpose. Indeed, there is no objective evidence of record suggesting that one should look to improve Stanton with a display as described in Nappholz. In addition, while the Final Office Action notes that an automobile may include an

Page 3 Dkt: 279.B31US2

example of a deadfront status indicator (*see* page 3), Appellant respectfully submits that this does not mean that one of ordinary skill in the medical device field would look to an automobile to "improve" the device disclosed in Stanton, particularly where there is no objective evidence of record of any recognition in the art of record of any serious limitation of the device of Stanton. Nothing in Stanton or Nappholz teaches the legally required desirability of their combination. *See In re Sang Su Lee*, 277 F.3d 1338; 61 U.S.P.Q.2D 1430 (Fed. Cir. 2002) (motivation to combine references must be supported by evidence in the record); *See also n re Mills*, 16 USPQ2d 1430 (Fed. Cir. 1990); M.P.E.P. § 2143.01. Instead, the rejection's asserted "motivation to combine" appears to be nothing more than the use of impermissible hindsight based on Appellant's own patent application in an effort to justify such a combination.

Moreover, the Examiner apparently equates an LED with a graphical or pictorial indicator. (*See* Advisory Action at Continuation of 11.) However, these two elements cannot be equated. There are many advantages to using a graphical or pictorial icon as opposed to a mere bare LED light. For example, such icons could use internationally accepted and recognized symbols. Where a bare LED indicator must rely other sources of information to permit the user to correctly interpret a signal (for example, an associated label printed next to the LED, or the user's understanding of what certain patterns of LED blinks indicate), a graphical or pictorial indicator does not have these serious inherent limitations. Moreover, the use of a backlit icon, as described in the Appellant's application, has the additional advantage of being able to quickly and completely communicate the intended message in situations where a bare LED cannot. For example, a bare LED with nearby descriptive text may be inadequate in low-light situations. Also, a bare LED with complex flashing intervals may be difficult for elderly or users with a diminished capacity to correctly interpret. Finally, the use of an icon has the advantage of being language-neutral. For at least these reasons, the Examiner's equating of a bare LED with a backlit deadfront icon is unfounded and inaccurate.

In sum, because the cited combination of Stanton and Nappholz fail to set forth all elements recited or incorporated in the present claims and because no evidence of any motivation or suggestion to combine the references has been objectively established, Appellant respectfully submits that there is no *prima facie* case of obviousness of claims 1-20. Therefore, Appellant respectfully requests reversal of all bases of rejection of all claims.

Serial Number: 10/749,093

Filing Date: December 17, 2003

Title: PATIENT CONTROLLED THERAPY MANAGEMENT AND DIAGNOSTIC DEVICE WITH HUMAN FACTORS INTERFACE

## **CONCLUSION**

The applicant respectfully submits that all of the pending claims are in condition for allowance, and such action is earnestly solicited. The Examiner is invited to telephone the below-signed attorney at (612) 373-6951 to discuss any questions which may remain with respect to the present application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

RICHARD E. STEIN ET AL.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.

P.O. Box 2938

Minneapolis, MN 55402

(612) 373-6951

Date April 19, 2006

Suneel Arora

Reg. No. 42,267

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop AF, Commissioner for Patents,

P.O. Box 1450, Alexandria, VA 22313-1450 on this